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J.D

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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IM22/1012

EXAMINER

LOVERING, R

ART UNIT

PAPER NUMBER

1712

15

DATE MAILED: 10/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/382,561

Applicant(s)

SUTTON ET AL.

Examiner

LOVERING

Group Art Unit

1712

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- ☒ Responsive to communication(s) filed on JULY 23, 2001
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 20-38 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 20-25 AND 30-34 is/are rejected.
- ☒ Claim(s) 26-29 AND 35-38 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some* ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 13 ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 20, 21 and 30 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Stein et al. 6,264,959, esp. patent claims; and Ex's 7-22.

4. Claims 22-25 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stein et al. above. The especially pertinent portions of Stein et al. are pointed out in the preceding paragraph. As to claims 22-24 and 31-33 herein, while Stein et al. do not specifically disclose particle sizes between 1 and 5 μm or interquartile ranges of 3 or 3 μm , it would have been obvious to one skilled in the art at the time applicant's invention was made to choose a suitable or optimum value or range of particle size(s) within the Stein et al. range of 1-10 μm . Assuming arguendo same difference in size between the claimed particles (such as capsules and those of the reference), applicant has shown no criticality in any such difference. See In re

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Arnold, 137 USPQ 330. As to claims 25 and 34 herein, while Stein et al. do not specify that their microparticles are sterile, one skilled in the art would have been motivated to sterilize the microparticles of Stein et al. because they are intended to be administered to human subjects.

5. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 is indefinite, inaccurate and improper in stating "said water-soluble material is a carbohydrate", when claim 28 (upon which it depends) states "said water-soluble material is a human protein or fragment or recombinant thereof. [Claim 30 should depend upon claim 20].

6. Claim 30 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. See rationale^e of preceding paragraph.

7. Claims 26-29 and 35-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record doesn't disclose or fairly suggest the compositions of claims 26-29 and 35-38, and the obviousness-type double patenting rejections have been overcome by terminal disclaimer.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lovering whose telephone number is (703) 308-0443.

The examiner can normally be reached on Mon. - Fri. from 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Dawson, can be reached on (703) 308-2340. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Examiner Lovering/om
October 11, 2001

Richard D. Lovering
RICHARD D. LOVERING
PRIMARY EXAMINER
GROUP ~~1200~~ 1700